

# Appendix A

## Sterilization Consent Form Comments (OS-0937-0166)

Date	Organization/Individual	Comments	HHS' Response
7/26/18	Ohio Department of Medicaid	<ul style="list-style-type: none"> <li>• There seems to be much confusion around the <b>requirement for the form</b> when the sterilization was not elective and the result of emergency medical conditions and related services.</li> <li>• Age of 21 mandate under these same emergent conditions.</li> </ul>	See 50.203(d) At least 30 days but not more than 180 days have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery, if at least 72 hours have passed after he or she gave informed consent to sterilization. In case of premature delivery, the informed consent must have been given at least 30 days before <b>the expected date of delivery.</b>
9/12/18	Certification Commission for Healthcare Interpreters (CCHI)	<ul style="list-style-type: none"> <li>• Readability – written at a 9<sup>th</sup> grade reading level, font type, font size, line spacing, and column width</li> <li>• Interpreter’s statement – “current interpreter statement violates the ethics and standards of practice that interpreters must follow.”</li> <li>• Translation vs. interpretation</li> <li>• Consent form does not adequately address the accessibility needs of people with disabilities and should be inclusive of sign language and other communication methods.</li> <li>• Recommended revision of the interpreter statement is same as NCIHC listed below.</li> </ul>	These comments are out of scope. It would be acceptable for providers to develop a fact sheet for patients explaining the content of the form at a lower reading level; however, the current form must be used and submitted when federal funds are requested to pay for the sterilization.
9/14/18	Antelope Memorial Hospital Nebraska	<ul style="list-style-type: none"> <li>• Is this service covered if the patient goes into early labor (38 weeks) and not “necessarily” a premature delivery but before the 30 day signature?</li> </ul>	See regulation 50.203(d); consent must have been given at least 30 days before “expected” date of delivery.
9/14/18	National Council on Interpreting in Healthcare (NCIHC)	<ul style="list-style-type: none"> <li>• 9<sup>th</sup> grade reading level</li> <li>• Overall readability (font type, font size, line spacing, and column width)</li> <li>• Interpreter’s statement: Translation versus interpretation, “An interpreter serves as a conduit handling language and can only attest that they accurately interpreted the</li> </ul>	These comments are out of scope. It would be acceptable for providers to develop a fact sheet for patients explaining the content of the form at a lower reading level; however, the current form must be used and submitted when federal funds are requested to pay for the sterilization.

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		<p>information to the best of their knowledge and ability.”</p> <ul style="list-style-type: none"> <li>• Recommendation: the interpreter statement to be accessible in “foreign language, sign language, and other communication methods.”</li> <li>• Recommendation – Revised interpreter statement: <i>I have accurately interpreted the information that was presented orally by the person obtaining this consent to the individual to be sterilized. As requested by the person obtaining consent, I have also:</i></li> </ul> <p>__ sight translated the consent form into _____ (insert language); or __ interpreted a summary of the form into _____ (insert language) or an alternative format as communicated by the person obtaining the consent to the individual to be sterilized.</p>	
9/15/18	Metro Health	<ul style="list-style-type: none"> <li>• Elimination of waiting periods</li> <li>• Define ‘premature delivery’ in the form relates to patients who deliver earlier than 40 weeks</li> <li>• Add ‘cesarean section’ be added to the term “emergency abdominal surgery” to help clarify for patients what is being stated in the form.</li> </ul>	These comments are out of scope. It would be acceptable for providers to develop a fact sheet for patients explaining the content of the form at a lower reading level; however, the current form must be used and submitted when federal funds are requested to pay for the sterilization.
9/16/18	California Healthcare Interpreting Association (CHIA)	<ul style="list-style-type: none"> <li>• 9<sup>th</sup> grade level</li> <li>• Issues with interpreter’s statement (see recommended revision NCIHC comments above)</li> <li>• Use of the word translation vs. interpretation</li> <li>• Consider the literacy, readability, and accessibility impacts of any health IT integration of the form on people with low</li> </ul>	These comments are out of scope. It would be acceptable for providers to develop a fact sheet for patients explaining the content of the form at a lower reading level; however, the current form must be used and submitted when federal funds are requested to pay for the sterilization.

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		<p>literacy, with disabilities, and with limited English proficiency.</p> <ul style="list-style-type: none"> <li>• Recommend HHS always provide Medicaid patients with the option to use the current paper-based approach or a health IT-based approach.</li> </ul>	
9/17/18	American College of Obstetricians and Gynecologists	<ul style="list-style-type: none"> <li>• Rewrite the sterilization consent form to ensure comprehension at an appropriate reading level.</li> <li>• Amend the interpreter statement to focus on interpretation versus translation and make the sterilization consent form available in multiple languages.</li> <li>• Recalculate the estimated burden of the sterilization consent form to include the impact on ob-gyns, other health care providers, medical staff, and health care institutions.</li> <li>• Develop processes to integrate the sterilization consent form into existing inpatient and outpatient electronic health records and make these systems interoperable.</li> <li>• Undertake formal rulemaking to overhaul in its entirety the federally-mandated sterilization consent form and related waiting period for sterilizations in federally-financed programs. Extend the current form's expiration date for a maximum of twelve months while rulemaking is conducted.</li> </ul>	These comments are out of scope. It would be acceptable for providers to develop a fact sheet for patients explaining the content of the form at a lower reading level; however, the current form must be used and submitted when federal funds are requested to pay for the sterilization.
9/17/18	National Latina Institute for Reproductive Health (NLIRH)	<ul style="list-style-type: none"> <li>• Asking an interpreter to attest that a patient understands a form or understands statements made by a medical provider seeking the patient's informed consent violates the ethics and standards of practice</li> </ul>	These comments are out of scope. It would be acceptable for providers to develop a fact sheet for patients explaining the content of the form at a lower reading level; however, the current form must be used and submitted when federal funds

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		<p>that an interpreter must follow.</p> <ul style="list-style-type: none"> <li>• Translation involves different skills and abilities than interpretation, which is a process of understanding and analyzing a spoken or signed message and re-expressing that message faithfully, accurately, and objectively in another language, taking the cultural and social context into account.</li> <li>• Recommend HHS amend the interpreter statement to cover language interpreting in a foreign language, sign language, and other communication methods.</li> <li>• Recommend using the singular pronoun “they” and “their” in place of “he/she” and “his/her,” respectively.</li> <li>• The Form’s text is written at a ninth grade reading level, which exceeds the recommended level for patient education and informed consent materials.</li> <li>• Recommend HHS consider the font type, font size, line spacing, and column width of the Form to improve its overall visual readability the Form contains some typos, grammatical errors, and inaccuracies that should be corrected. (see NLIHR letter)</li> </ul>	<p>are requested to pay for the sterilization.</p>
<p>9/17/18</p>	<p>National Health Law Program (NHLP) representing:            National Health Law Program            ACT for Women and Girls            American Atheists            American Civil Liberties Union            American Medical Women's Association            Asian &amp; Pacific Islander American Health Forum</p>	<ul style="list-style-type: none"> <li>• Readability challenges – 9<sup>th</sup> grade reading level</li> <li>• Issues with interpreter’s statement – Limited English Proficiency and disabilities (see NCIHC interpreter statement recommendation above.)</li> <li>• Need for Gender Inclusive Language – amend “he/she” pronouns to “they” and “their”</li> <li>• Recognizing Supported Decision Making – gives an individual with a disability a chance to consult with a person of their choosing to</li> </ul>	<p>These comments are out of scope. It would be acceptable for providers to develop a fact sheet for patients explaining the content of the form at a lower reading level; however, the current form must be used and submitted when federal funds are requested to pay for the sterilization.</p>

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<p>Asian Americans Advancing Justice - Los Angeles California Latinas for Reproductive Justice California Women's Law Center Center for Reproductive Rights Center on Reproductive Rights &amp; Justice Disability Rights Education and Defense Fund Equality California FORGE, Inc. In Our Own Voice: National Black Women's Reproductive Justice Agenda Jacobs Institute of Women's Health Legal Action Center Medical Students for Choice NARAL Pro-Choice America National Asian Pacific American Women's Forum (NAPAWF) National Center for Lesbian Rights National Council of Jewish Women National Equality Action Team (NEAT) National Family Planning &amp; Reproductive Health Association National Institute for Reproductive Health (NIRH) National Latina Institute for Reproductive Health National LGBTQ Task Force National Network of Abortion Funds National Organization for Women National Partnership for Women &amp;</p>	<p>make an informed decision.</p> <ul style="list-style-type: none"> <li>• Label fill-in-the-blank spaces with required information, i.e. (name, date, etc.)</li> <li>• "The request for race/ethnicity should explain why the data is being collected, and reiterate the confidential nature of the information collection. We also recommend the inclusion of a fill-in-the-blank option. Also, the purpose of the text contained inside the first parenthetical ("Ethnicity and Race Designation") is unclear, and should be struck. In addition, the text in the second parenthetical ("please check") should be modified to allow the patient to check all of the race/ethnicity categories that apply."</li> <li>• Interpreter's statement add "the" before sterilization procedure.</li> <li>• Health IT (automated collection techniques) Consider the literacy, readability, and accessibility impacts of any health IT integration of the form on people with low literacy, people with disabilities, and limited English proficient individuals.</li> <li>• Recommend always providing Medicaid patients with the option to use the current paper-based approach or a health IT-based approach.</li> </ul>	
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	Families National Women's Health Network National Women's Law Center Nevada County Citizens for Choice Planned Parenthood Federation of America and Planned Parenthood Action Fund Population Connection Positive Women's Network - USA Power to Decide SIA Legal Team URGE: Unite for Reproductive & Gender Equity Western Center on Law and Poverty		
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